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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/518,859

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Kazuhiko Inoue

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EXAMINER

LISTVOYB, GREGORY

ART UNIT

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1711

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/518,859

Applicant(s)

INOUE ET AL.

Examiner

Gregory Listvoyb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-130 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 43-76 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 77-130 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/28/2005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

The present action, restarting period for response, is issued upon Attorney request. The Applicant has not received a complete copy of the Action due to a scanning error.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 43-76, drawn to biodegradable resin.

Group 2, claim(s) 77-118, drawn to resin composition and molded body

Group 3, claim(s) 119-130, drawn to methods of producing biodegradable resins.

The inventions listed as Groups 1, 2 and 3 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention as claimed in independent claim 43 does not define a special technical feature distinguishing the claimed invention over the prior art. The biodegradable resin as claimed in claim 43 are fully anticipates by, for example, disclosure of US Patent 6018033 to Chen.

During a telephone conversation with Paul Essatto on 1/19/07 a provisional election was made with traverse to prosecute the invention of Inoue et al, claims 43-76. Affirmation of this election must be made by applicant in replying to this Office action. Claim 77-130 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

Claims 43-48, 51-53, 55-57, 59-61 rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al (US patent 6018033), herein Chen.

Regarding Claims 43-48, 53, 57, 60, 61, Chen discloses a modified Saccharide, Polyester, Polyalkylene Oxide (polyols) and Aminoacid based biodegradable thermo-reversible crosslinked resin, which is covalently bonded by Diels-Alder type linkage, which is cleaved at temperatures above 120C (Abstract, Column 6, line 35, Figures 1

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and 12, Examples II-1, III-1 and III-2). A functional group can be dienyl, carboxyl, hydroxyl and others (Examples III-1 and III-2 and Column 7, line 35).

Regarding Claim 52, a biodegradable resin can contain linear and branched structure (column 5, line 25).

Regarding Claims 51, 55 and 59, Chen discloses cross-linked density in terms of Swelling Ratio. This ratio changes within a broad range of 5-90%. According to Flory, cross-link frequency can be calculated from the above parameter (more crosslink frequency corresponds with less swelling ratio). In examiner's opinion, Chen's composition internally possesses cross-linked density to meet the limitations of the above Claims.

Claims 43, 45, 49 and 52 rejected under 35 U.S.C. 102(b) as being anticipated by Onwumere et al (US patent 5491210), herein Onwumere.

Onwumere discloses a modified polycaprolactone (comprising a modified body of lactic acid) biodegradable thermo-reversible crosslinked resin, which is covalently bonded by Diels-Alder type linkage, which is cleaved at temperatures above 120C (Abstract, Column 4, line 30).

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Claims 43-45 rejected under 35 U.S.C. 102(b) as being anticipated by Kobayashi et al (US patent 6207762), herein Kobayashi.

Kobayashi a discloses a biodegradable thermally reversible (at 100-250C, Claim 16) crosslinked polyester-based composition (Column 3, line 60) with carboxyl-alkenoxo bond (Claim 4).

Claims 43-45 rejected under 35 U.S.C. 102(b) as being anticipated by Takao et al (JP publication 11-035675), herein Takao.

Takao discloses a thermo-reversible cross-linked composition, comprises a biodegradable polyester and contains alkenyl hydroxyl-carbonyl link. The above composition cleaves at 130-160C (Abstract, line 0010 and 0018 and Formula 1).

Claims 43-45 rejected under 35 U.S.C. 102(b) as being anticipated by Chino et al (US patent 6746562 and JP2002-2060422), herein Chino.

Chino discloses a thermo-reversible, crosslinkable elastomer, having stable cross-linked structure at room temperature and plasticity and moldability at mold temperature. (Abstract). The cross-linking can be achieved with different methods, including Diels-Alder (reaction of maleic anhydride with diene rubber, Column 8, line

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55). Therefore, Chino's composition inherently meets the limitation of cleaved temperature over 120C.

Some of Chino's materials, such as aliphatic polyesters are biodegradable (Column 5, line 50).

Claim Rejections - 35 USC § 103

Claim 49, 54 and 63-65 rejected under 35 U.S.C. 103(a) as being unpatentable over Chen in combination with Helmus et al (US publication 2004/0093080 and WO 0154745), herein Helmus

Chen discloses a modified Saccharide, Polyester, Polyalkylene Oxide (polyols) and Aminoacid based biodegradable thermo-reversible crosslinked resin, which is covalently bonded by Diels-Alder type linkage, which is cleaved at temperatures above 120C (Abstract, Column 6, line 35, Figures 1 and 12, Examples II-1, III-1 and III-2). A functional group can be dienyl, carboxyl, hydroxyl and others (Examples III-1 and III-2 and Column 7, line 35).

Chen does not disclose a biodegradable resin based on polylactic acid.

Helmus discloses a coatings in which the bioactive compound can be reversible (e.g., through a cleavable linker) to polylactic acid (Page 6, line 0068).

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It would be obvious to a person with ordinary skills in the art to use a modified polylactic acid derivative in Chen's composition, since the esters, based on the above material is most commonly used and economical biodegradable material.

Claims 43, 50 and 69 rejected under 35 U.S.C. 103(a) as being unpatentable over Chino.

Regarding claims 50 and 69, Chino teaches a resin, based on succinic acid and succinic anhydride (Column 27, line 30), but not specifically discloses polybutylene succinate (PBS). PBS is well known as a most commonly used biodegradable plastic with excellent mechanical properties, similar to PET.

It would be obvious to a person with ordinary skills in the art to use a modified PBS acid derivative in Chino's composition, since PBS is readily commercially available biodegradable plastic with excellent mechanical properties.

Claim 43, 47, 48, 62, 66-67 and 70-76 rejected under 35 U.S.C. 103(a) as being unpatentable over Chen in combination with Kozo (JP publication 2000-28105) herein Kozo.

Chen discloses a modified Saccharide, Polyester, Polyalkylene Oxide (polyols) and Aminoacid based biodegradable thermo-reversible crosslinked resin, which is

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covalently bonded by Diels-Alder type linkage, which is cleaved at temperatures above 120C.

Chen does not teach ion-crosslinking compositions.

Kozo discloses polysaccharide-based ion-crosslinking film and its production (Abstract). Kozo teaches that in order to create ion-crosslinking polysaccharide composition divalent ions added to the composition.

It would be obvious to a person with ordinary skills in the art to add divalent metal ions to Chen's composition to create both covalent and ionic reversible crosslinked structure. It would diversify a number of applications for Kozo's composition. For instance, Kozo's composition can be used in drug delivery systems and other *in-vivo* applications.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory Listvoyb whose telephone number is (571) 272-6105. The examiner can normally be reached on 9am-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gregory Listvoyb
Examiner
Art Unit 1711



James J. Seidleck
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